**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| **IN RE NEOVASC INC. SECURITIES LITIGATION** | **Case No. 7:20-cv-09313-PMH** |
| | **CLASS ACTION** |
| **THIS DOCUMENT RELATES TO: ALL ACTIONS** | **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** |
| | **JURY TRIAL DEMANDED** |

## CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Lead Plaintiff Pratap Golla ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's Consolidated Amended Class Action Complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys. This investigation included, among other things: (1) a review of the Defendants' public documents; (2) conference calls and announcements made by Defendants; (3) United States Securities and Exchange Commission ("SEC") filings; (4) wire and press releases published by and regarding Neovasc Inc. ("Neovasc" or the "Company"); (5) analysts' reports and advisories about the Company; (6) information provided by the Company to the Food and Drug Administration ("FDA") and information about the Company's interactions with the FDA; (7) and other publicly available information. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons who purchased or otherwise acquired Neovasc common stock between October 10, 2018 and January 15, 2021, both dates inclusive (the "Class Period") seeking to recover damages caused by Defendants' violations of the federal securities laws and pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. Neovasc is a biotechnology company based in Richmond, British Columbia that seeks to manufacture medical devices for cardiovascular therapies. It is a very small company with only 6 employees considered the core members of management, including the four other Defendants named in this Action. As of the end of fiscal year 2020, the Company had 71 employees.

3. The Company hopes to develop two therapies, the Reducer™ ("Reducer") and Tiara™ ("Tiara"). Tiara is still in clinical trials and has not been approved in any country while the Reducer is not approved in the United States despite a decade long effort by the Company to bring it to market. Hence, the Reducer is the Company's core product and only source of revenue from the small amount of Reducer sales in a handful of foreign countries.[1]

4. In 2010, the Company approached the FDA and sought its permission to conduct a premarket clinical study (hereafter "the COSIRA trial") in an effort to demonstrate the safety and efficacy of the Reducer. The FDA categorically told the Company at that time that the COSIRA

[1] As explained more fully below, the Reducer is a balloon expandable, metal mesh device implanted in the coronary sinus using needle puncture techniques. It is intended to alleviate the symptoms of refractory angina by narrowing the coronary sinus and creating backward pressure in the heart that improves the volume of blood that flows through the heart.

trial had serious flaws. For example, the FDA pointed out that the COSIRA study had an inappropriately subjective endpoint based on angina symptoms when a rigorous treadmill exercise test was the standard metric used in trials for similar devices. Dissatisfied with the FDA's criticisms, Defendants disregarded its advice and chose to conduct the COSIRA trial abroad.

5. In 2016, the Company again approached the FDA to request approval for a larger trial known as COSIRA II. While the FDA told the Company that it would allow COSIRA II to proceed, it also expressly indicated that COSIRA II would not be sufficient to demonstrate efficacy and that even further additional data would be needed.

6. However, the Company did not initiate COSIRA II because it was hit with a crippling $112 million judgment in a federal trial in Massachusetts for stealing another company's trade secrets in an attempt to develop Tiara. The judgment was subsequently affirmed by the United States Court of Appeals for the Federal Circuit in November 2017. This massive liability immediately drained $70 million in cash from the Company's balance sheet, and the Company was on the verge of declaring bankruptcy in late 2017 because it could not afford to pay the remaining $42 million owed on the judgment.

7. To avoid bankruptcy, the Company entered into debt-and-equity financing that was extremely onerous, caused massive dilution, and completely handcuffed Neovasc's ability to raise capital. During the Class Period, in filings with the SEC, earnings conference calls, and in communications with the media, Defendants admitted that these financing arrangements significantly restricted Neovasc from raising additional funds needed to complete COSIRA II, strained its cash position, and threatened its ability to remain a going concern.

8. Robust, well-controlled clinical trials to support an application to market a medical device in the United States are very expensive and time consuming. A well-controlled and reliable

clinical trial utilized to support the Reducer's efficacy would take five years to complete and cost tens of millions of dollars with no guarantee that its results would be successful or that the FDA would ultimately approve the device.

9. In October 2018, Defendants convinced the FDA to designate the Reducer as a breakthrough device. While FDA regulations make it clear that this designation does not mean the device is safe or effective, Defendants repeatedly hyped the designation as a proxy for the Reducer's ability "to provide significant benefits to patients suffering from refractory angina." What the designation actually meant, however, was that Neovasc would have intensive interactions with the FDA to expedite review. The level of interaction with the agency during the pre-approval stage was leaps and bounds ahead of the regular interaction for other devices, and included a specialized review team at the FDA, a senior officer at the FDA assigned to manage interactions with the agency, and targeted discussions between the Company and the FDA that made it virtually certain that there could be no miscommunication regarding the agency's serious concerns about the clinical data used to support the Reducer.

10. On February 20, 2019, the Company announced that the FDA "recommends collection of further pre-market clinical data."

11. On this news, the price of the Company's common stock declined by $0.10, or 1.47%, to close at $6.70 per share on February 20, 2019. The February 20, 2019 press release, however, was materially misleading when made because the FDA had already told the Company that the COSIRA trial was deficient, and additional pre-market clinical data was not "recommended" but required.

12. On July 12, 2019, the Company hyped the FDA's suggestion that perhaps it should seek a humanitarian exemption for the Reducer that could allow it to market the device to a subset

of no more than 8,000 angina patients. A humanitarian device exemption is granted under FDA regulations even if the device cannot meet the standards for efficacy if it otherwise meets the restrictive criteria for the exemption and is limited to no more than 8,000 patients in the United States.

13. Defendants, however, failed to disclose that this exemption does not require a demonstration of efficacy or that the FDA had suggested the alternative because the clinical data for the Reducer failed to demonstrate efficacy.

14. Throughout the Class Period, Defendants repeatedly misrepresented the results of the COSIRA study that the FDA had warned it for almost a decade was flawed and did not meet basic standards for a well-controlled, clinical trial such as the collection of reliable data from animal studies conducted before the device can be implanted in humans or the use of a treadmill exercise test that the FDA expects the sponsor to use in trials for similar devices intended to treat similar conditions or diseases.

15. In addition, Defendants misled investors regarding the feedback received from the FDA concerning its views about the clinical data utilized to support the efficacy of the Reducer, and needlessly exaggerated the preliminary results from an incomplete, observational study of patients implanted with the Reducer abroad (hereafter "the REDUCER-I") even though this study had serious execution problems, relied on extremely limited data, and was not considered by the FDA to be an adequate substitute for a robust, well-controlled clinical trial conducted prior to approval.

16. Unable to conduct a proper clinical trial given the vast amount of resources and time required, which Neovasc did not have, Defendants made a conscious decision in December 2019 to submit a Premarket Approval Application ("PMA") seeking the FDA's approval to market

the Reducer in the United States even though Defendants had been told their clinical data was insufficient and consequently were aware of a very high risk that the FDA would reject the application. Defendants did not disclose the risks of this strategy to investors, or tell the truth about the decade-long negative feedback from the FDA concerning the clinical data for the Reducer.

17. Instead, after the PMA was submitted, between December 2019 and October 2020, Defendants continued to tout various facets of the clinical data utilized to support the PMA for the Reducer but failed to disclose the FDA's serious criticisms of the COSIRA trial or the REDUCER-I observational study. The omission of these facts rendered Defendants' positive statements misleading.

18. On October 27, 2020, at the invitation of the FDA, an advisory committee of experts held a public meeting to discuss and vote on the safety and efficacy of the Reducer and its risk-benefit profile. At this virtual meeting, multiple members of the FDA review team with oversight over the PMA for the Reducer presented their views on the clinical data to support the PMA. The testimony of FDA reviewers was individually troubling, and collectively devastating. For example, the review team stated that:

- The perfunctory animal studies, hailed by the Company as providing "excellent results," did not demonstrate a narrowing of the coronary sinus—the exact objective of the Reducer in human subjects;

- The COSIRA trial was structurally flawed and not reflective of the patient population in the United States because it was a small study and virtually all of its subjects were white males over the age of 65;

- The COSIRA trial's secondary endpoints had a serious potential for false positive findings, and missing data from the trial made interpretation of efficacy difficult;

- The COSIRA trial had a substantial placebo effect, and the lack of a formal assessment on blinding or an exercise tolerance test rendered the results unreliable;

- The REDUCER-I observational study had no control group, severely limited data given that only 20 patients in a single country had follow-up data at the five-year mark, and the FDA did not consider an incomplete, observational study of patients implanted with the Reducer abroad to be an adequate substitute for a robust, well-controlled clinical trial prior to approval.

19. Most importantly, multiple members of the FDA review team made it clear at the advisory committee meeting that Neovasc was expressly warned by the FDA of the flaws in the clinical data utilized to support the PMA. The FDA's lead presenter told the advisory committee that, in 2010, the FDA rejected the application to conduct the COSIRA trial in the United States due to flaws in its design made known to the Company. He further testified that, in 2017, the FDA expressed reservations about the COSIRA II trial and implored the Company to go beyond its parameters to demonstrate efficacy. The lead presenter on the Reducer's clinical data explicitly stated that the Company was expressly told about the FDA's concerns, and those concerns were raised in writing and during multiple in-person and teleconference interactions.

20. At the end of the advisory panel proceeding, the advisory committee concurred with the FDA's criticisms, and multiple members of the committee stated on the record that the outcome may have been different if the Company had bothered to listen to the FDA's advice and conduct a proper trial years before the PMA was submitted.

21. The next day, on October 28, 2020, the Company announced that the advisory committee had voted 17 to one against whether the Company's submission established the efficacy of the Reducer and 13 to three against whether the benefits of the device outweighed its relative risks. These decisions were based on a detailed examination of the structure and results of the COSIRA trial, and the advisory committee's agreement with the FDA that the REDUCER-I observational study could not reasonably be considered a substitute for a well-controlled, clinical trial and that Defendants' reliance on it amounted to placing the cart before the horse.

22. On this news, the price of the Company's common stock fell $0.77 per share, or 42%, to close at $1.06 per share on October 28, 2020, on unusually heavy trading volume.

23. On November 6, 2020, the Company held a conference call to announce its financial results for the third quarter of 2020. During this conference call, Defendant Fred Colen, the Company's Chief Executive Officer ("CEO") completely dissembled. At first, Colen made an objectively false statement that was contradicted by the Company's own disclosures made days earlier when he claimed that the advisory committee "gave a positive mark as related to benefit over risk." Later, Colen offered post hoc justifications for Defendants' decision to submit a PMA despite already having been told that the FDA believed their sole pivotal clinical trial to be flawed and insufficient, crucial risks withheld from investors during the Class Period. Specifically, Colen misleadingly leaned on published Guidances from the FDA to support Defendants' decision to submit a PMA for the Reducer with flawed clinical data. These excuses were not based in fact. The published Guidances that Colen referenced in no way supported Defendants' gamble to submit data they were already told was insufficient, and in no way undercut the other feedback that the Company had already received from the FDA.

24. For example, Colen cited FDA Guidance from 2015 even though the FDA told the Company to again collect additional preclinical data in the beginning of 2019, and then raised serious efficacy concerns when it suggested that Defendants should explore submitting an application for humanitarian reasons if the trial could not demonstrate the effectiveness of the device.

25. Colen also mentioned FDA Guidance from August 2019 to claim that Defendants' reliance on the REDUCER-I observational might be appropriate. In fact, the August 2019 FDA Guidance said the exact opposite, making clear that ***premarket*** evidence must meet the

performance goal of the clinical trial ***before*** the FDA considers observational data from patients already implanted with the device.

26. On January 15, 2021, the Company announced that the FDA had rejected the PMA for the Reducer.

27. On this news, the price of the Company's common stock fell by 8%, to close at $1.10 per share on the next trading day, which was January 19, 2021.

28. While investors suffered losses, Defendants lined their own pockets during the Class Period. Defendant Colen and the Company's Chief Financial Officer ("CFO"), Defendant Christopher Clark, received hundreds of thousands of dollars in bonuses directly tied to illusory milestones associated with the Reducer. These bonuses were nearly equal in amount to their base salaries.

29. As a result of Defendants' wrongful acts and omissions, and the resulting precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

## JURISDICTION AND VENUE

30. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

31. This Court has jurisdiction over the subject matter of this Action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

32. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Many of the acts and transactions that constitute the alleged violations of the law, including the dissemination to the public of materially false and

misleading statements of fact, occurred in this District where the Company's securities traded on the NASDAQ Capital Market ("NASDAQ").

33. In connection with the acts, conduct and other wrongs alleged in this Consolidated Amended Class Action Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange located in this Judicial District.

## PARTIES

34. Plaintiff acquired Neovasc common stock at artificially inflated prices during the Class Period and was damaged upon the disclosure and/or materialization of the risks concealed by Defendants' Class Period misrepresentations and omissions.

35. Defendant Neovasc is incorporated under the laws of Canada with its principal place of business located in British Columbia, Canada. It is a small company with only 6 employees, including the senior executives named in this Action considered as part of the Company's core "management." Neovasc's common stock trades on the NASDAQ under the ticker symbol "NVCN."

36. Defendant Colen has served at all relevant times as the Company's CEO. Colen has an engineering degree with a specialization in biomedical technology, previously served as the CEO of another medical device manufacturer in the cardiac therapy space, and also served as the Chief Technology Officer of Boston Scientific Cardiac Rhythm Management. This background and experience put Colen in a position to know both about the Reducer's potential for safety and efficacy as well as the FDA's regulatory framework for the approval of medical devices.

37. Defendant Clark has served at all relevant times as the Company's CFO. Clark claims to be a "highly sought after consultant for biotechnology startups," and touts that he was "instrumental in the initial and ongoing development of Neovasc as a publicly traded company." *See* Clark's Biography, available at https://www.neovasc.com/management/.

38. Defendant Bill Little ("Little") was hired as the Company's COO in November 2019 and served in that capacity for the remainder of the Class Period. Little has worked in numerous pharmaceutical companies dedicated to interventional cardiology and structural heart disease.

39. Defendant Shmuel Banai ("Banai") is the Medical Director of Neovasc and served as the Medical Director of Neovasc Medical Limited, the predecessor company of Neovasc that initially developed the Reducer. Banai claims that he is "one of Israel's leading Cardiologists and a productive researcher." *See* Banai's Biography, available at https://www.neovasc.com/management/. As someone who was involved in structuring Neovasc's clinical trials for the Reducer from the start, there is no question that Banai has the knowledge and experience in clinical trials for medical devices as well as the FDA's regulatory landscape for seeking approval for a device.

40. The Defendants referenced above in ¶¶ 36-39 are sometimes referred to herein collectively as the "Individual Defendants."

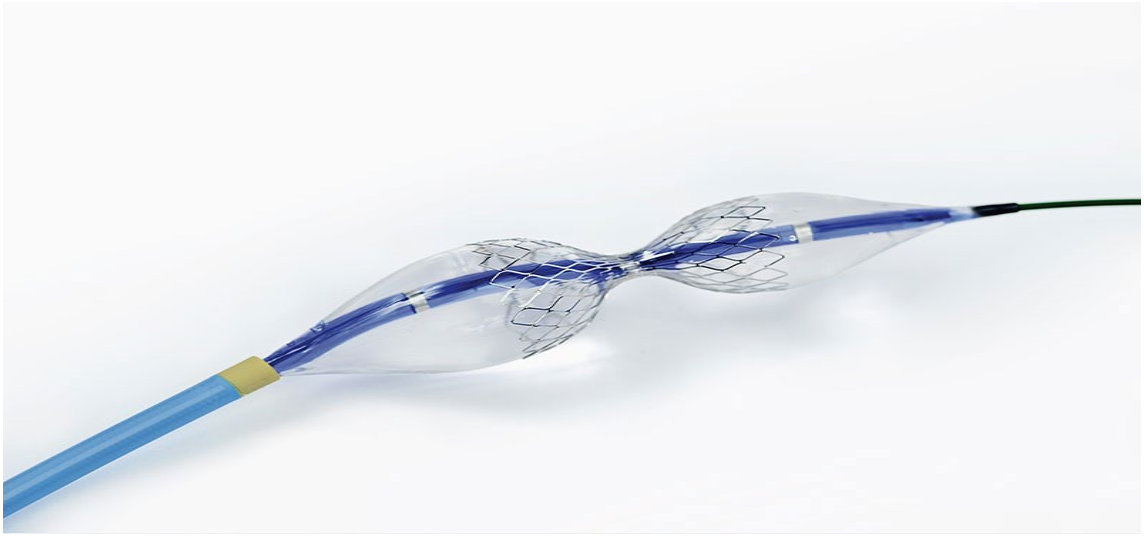
41. The Individual Defendants possessed the power and authority to control the contents of Neovasc's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings, earnings conference calls, and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be

corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

## SUBSTANTIVE ALLEGATIONS

### Background

42. Neovasc is a biotechnology company based in Richmond, British Columbia that seeks to manufacture medical devices for the cardiovascular marketplace. The Company has two products under development, the Reducer and Tiara. Tiara is a catheter-based treatment for mitral valve regurgitation, a condition that can lead to heart muscle damage. The Tiara is still in early clinical trials and has not been approved in any country. The Reducer is an hour-glass shaped, balloon expandable, stainless steel metal device, implanted in the coronary sinus using needle puncture techniques. It is intended for patients with refractory angina, and purports to narrow the coronary sinus, creating backward pressure in the heart that improves blood perfusion and potentially helps relieve chest pain, shortness of breath, and other symptoms associated with refractory angina:



43. Unlike Tiara, the Reducer was the Company's core product during the Class Period. The Company marketed the product in some European countries and other parts of the world and derived a small amount of revenue from its sales. Neovasc has had no other approved products in any country since its inception. To try to support the safety and efficacy of the Reducer, the Company conducted preclinical animal studies, which Defendants repeatedly touted throughout the Class Period as a resounding success. In 2010, the Company approached the FDA to obtain an investigational device exemption ("IDE") for the Reducer, which would allow it to conduct a preclinical study in the United States for the unapproved device. At that time, the FDA expressed serious concerns about the clinical trial, now known as COSIRA. When Neovasc could not convince the FDA that the COSIRA trial would be robust enough to support the safety and efficacy profile of the Reducer, the Company ceased its efforts to obtain approval to conduct COSIRA in the United States and instead decided to conduct the COSIRA trial exclusively in Europe and Canada.

44. The COSIRA trial began enrollment in 2010 and was completed in 2013. It purported to be a randomized, double-blind, sham-controlled study to assess the safety and efficacy of the Reducer, with a primary endpoint of a two-class improvement in angina symptoms for

patients with severe angina six months after implantation of the device. Since the study's completion in 2013, Defendants have claimed that the COSIRA trial met its primary endpoint and have relentlessly touted its results to claim that the Reducer is both safe and effective.

45. After the Company convinced some countries to allow the Reducer to be marketed abroad, in 2016, Neovasc initiated an observational study known as REDUCER-I seeking to collect long-term data from European patients implanted with the Reducer. Neovasc intended to collect data from 400 patients but had only enrolled slightly over half this amount during the Class Period, so even this observational study was incomplete when the PMA was submitted seeking approval of the device in the United States.

46. On November 3, 2017, Neovasc received FDA approval of an IDE for another trial known as COSIRA II, a larger trial with 380 patients, in a multicenter, sham-controlled clinical study with up to 35 investigational centers across America. The COSIRA II trial was expected to cost the Company tens of millions of dollars and take up to five years to complete. That same month, however, a judgment against Neovasc for $112 million was affirmed by the United States Court of Appeals for the Federal Circuit. The Company subsequently financed payment of a portion of the judgment through the issuance of both debt and equity. The resulting financial instability left Neovasc unable to afford COSIRA II.

47. On December 18, 2018, Neovasc made a submission to the FDA to discuss moving forward with an application seeking to market the Reducer in the United States based on all clinical data that it had gathered to date over a 10-year period.

48. In February 2019, Neovasc announced that the FDA review team had told the Company that it "recommended" additional premarket blinded data before the Company submitted an application to market the device.

49. Despite the fact that the FDA's serious concerns about all the clinical data had not changed for nearly 10 years, the Company nevertheless submitted an application seeking approval of the Reducer on December 30, 2019 with knowledge of a very high risk of non-approval, but failed to disclose the high risk to investors or otherwise disclose the overwhelmingly negative feedback it received from the FDA.

**The Regulatory Process for Premarket Approval of Medical Devices**

50. The Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act ("FDCA") established regulatory classes for medical devices. The most regulated devices are in Class III. A Class III device is one that supports or sustains human life or purports to prevent impairment of human health or poses a potentially unreasonable risk of illness or injury.

51. Under Section 515 of the FDCA, Class III devices are subject to stringent premarket approval requirements that require a rigorous scientific review to ensure safety and efficacy of the device. A PMA provides a sponsor with a private license to market a specific medical device. A device that fails to meet PMA requirements is considered adulterated under the FDCA and cannot be sold to the public.

52. Pursuant to Section 513(a)(2) of the FDCA, the FDA must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from its use in determining whether to grant or deny a PMA. In particular, FDA regulations, including 21 CFR 860.7, require that a sponsor produce evidence of effectiveness of a medical device generally through well-controlled clinical studies. Any results from the clinical studies must be robust enough to provide the FDA with enough data to determine whether there is a reasonable assurance of safety and efficacy of the device.

53. Clinical testing is a multi-layered process that sometimes begins with preclinical animal studies to first-in-human use to large, randomized control trials that often require hundreds or thousands of subjects to produce a reliable result. In the context of a PMA application, this is a very rigorous and time-consuming inquiry into the risks and efficacy of the device, and the requirements are undoubtedly the most stringent.

54. The FDA has a pre-submission process to facilitate PMA applications and it encourages sponsors to establish early contact with the agency in "Pre-submission" meetings, which are otherwise known as "Q-sub" meetings. In order to conduct a pre-market clinical trial in the United States to prove safety and efficacy, a company must first obtain an IDE from the FDA. Early communication with the FDA allows the sponsor to negotiate clinical endpoints for any preclinical study, and keeps the sponsor informed of the FDA's expectations. While the FDA has not shut the door on considering data from trials conducted abroad, it still requires that foreign trials meet the regulatory standards for efficacy and support the use of the sponsor's device in patient populations in the United States and in accordance with the norms of medical practice, otherwise known as standard of care, in the country.

55. The FDA can also refer the PMA to an outside panel of experts pursuant to 21 CFR 814.44. Generally, novel devices are taken before the advisory panel for review and recommendation. If the PMA is referred to an advisory committee, the committee must hold a public meeting to review the application. The advisory committee then submits its report to the FDA, which contains its recommendation and the basis for the recommendation. The FDA usually takes the advisory committee's recommendation into account when it reaches a final decision on the PMA. However, the advisory committee's recommendations are not binding on the FDA, which always has the final word on whether to approve a PMA.

**The FDA's Breakthrough Devices Program**

56. The FDA's breakthrough devices program was established pursuant to the 21st Century Cures Act of 2016 to expedite the review process for novel devices that ***could*** potentially benefit patients from life-threatening or irreversibly debilitating conditions. This is a voluntary program where a sponsor can request the FDA to designate its device as a breakthrough technology if the device has the potential to provide for "more effective" treatment or diagnosis for a life-threatening or irreversibly debilitating condition or disease and meets one of the following criterion: (1) the device represents breakthrough technology, (2) no approved or cleared alternative exists, (3) the device may offer advantages over existing alternatives, or (4) the availability of the device is in the best interests of the patients.

57. Of critical importance, in order to preliminarily show that a device could potentially benefit patients with life threatening conditions or diseases, a manufacturer only needs to show that a device ***could*** treat or diagnose the condition based on unconfirmed preliminary data that does not necessarily meet the standard for the FDCA's or FDA regulations' requirements for efficacy because designation decisions by the FDA are naturally made prior to any market authorization of the device, which, in contrast, does require a clear demonstration of efficacy. And designation of a device as a breakthrough by no means indicates that it meets the regulatory requirements for safety and efficacy, and the designation can be withdrawn by the FDA at any time.

58. Breakthrough device designation does not lower or eliminate any FDA standards. Breakthrough devices still must meet the standards for safety and efficacy like any other device before they can be approved. This is clear from both the *FDA's Guidance for Industry: Breakthrough Devices Program* (December 18, 2018) as well as the comments of Dr. Samuel

Raben ("Raben"), the lead presenter on behalf of the FDA, at the advisory committee meeting held on October 27, 2020 to vote on the benefit-risk profile and safety and efficacy of the Reducer. At the advisory committee meeting, Dr. Raben emphasized at the outset that "[i]t is important for the Panel to note that while the Breakthrough Devices Program offers increased communication and collaboration with [the] FDA, it does not modify or reduce the statutory requirements for device approval. FDA still requires that the Reducer device demonstrate a reasonable assurance of safety and effectiveness." Tr. of the Advisory Committee Meeting held on October 27, 2020 at 76: 11-14.

59. Defendants repeatedly ignored this reality throughout the Class Period when they grossly exaggerated the Reducer's "breakthrough" designation, hyped its efficacy based on a deficient clinical trial conducted outside the United States, and failed to disclose the FDA's severe criticisms of that trial that were known to them for over a decade.

60. Breakthrough device designation does offer a sponsor, in Dr. Raben's words, "increased interaction with [the] FDA through several different mechanisms to help provide timely feedback in an effort to speed up the developmental process." Tr. of the Advisory Committee Meeting held on October 27, 2020 at 76: 5-7. This means regular, interactive and timely communication that includes submissions routed to a specialized review team at the FDA, a designated senior manager such as an Officer Director assigned to review a sponsor's submissions, priority review of all submissions, monthly or bimonthly status updates from the FDA and "Breakthrough Device Sprint Discussions" where the FDA offers expedited discussions with the purpose of reaching an agreement with the sponsor on a specific topic within a specified time period. The FDA describes Sprint discussions as an "intensive level of interaction" with the agency and provides specific guidance on how a sponsor can structure these discussions to reach

the most productive outcome. *See FDA's Guidance for Industry: Breakthrough Devices Program* (December 18, 2018), at p.18-19.

61. Defendants here had numerous Sprint discussions with the FDA regarding the Reducer throughout the Class Period, and Defendant Colen repeatedly referred to these Sprint discussions in earnings conference calls and healthcare conferences. Thus, there can be no dispute that Defendants had an "intensive level of interaction" with the FDA regarding the Reducer throughout the Class Period even if they chose to withhold the FDA's serious criticisms and negative feedback about the device from investors. For example, at the Credit Suisse Healthcare Conference held in Scottsdale, Arizona on November 13, 2019, Colen told the audience that the Company had many Sprint discussions with the FDA in advance of its PMA submission due to the Reducer's Breakthrough Device Designation.

62. Hence, there is no question that the Breakthrough Device Program provided Defendants with numerous opportunities to know about the FDA's continuing concerns about the clinical data throughout the Class Period, and this fact was subsequently confirmed by the FDA personnel at the advisory committee meeting, who repeatedly stated that the Company, in fact, was informed about the FDA's serious criticisms at every step of the way.

**The Humanitarian Device Exemption Program**

63. Humanitarian Use Devices ("HUD") are intended to benefit patients in the treatment of conditions or diseases that do not affect more than 8,000 individuals in the United States per year. HUDs are usually approved for devices that seek to treat pediatric populations or diseases and conditions that do not occur in pediatric populations "in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe." *See*

*FDA's Guidance for the Industry: Humanitarian Device Exemption (HDE) Program* (September 6, 2019) at p. 23.

64. Given the quantitative limits on the number of patients that the disease or condition affects to make the device eligible for the HDE, profits are extremely limited and the HDE offers little benefit to a biotechnology company eager to profit substantially from an alleged "breakthrough device."

65. Critically, a "HUD under an HDE is *exempt* from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under Section 514 and 515 of the" FDCA. *Id.* at 7 (emphasis in original).

66. After a decade of negative feedback from the FDA regarding the efficacy of data provided by the Defendants for the Reducer, in February 2019, the Company announced that the FDA had again told Defendants to collect additional pre-market blinded data before submitting the PMA for the Reducer.

67. On July 12, 2019, Neovasc released a press release stating that the FDA had now recommended that the Company may want to consider alternative approaches for approval for Class IV refractory angina patients or an alternative clinical trial for a broader refractory angina patient population. The Company further stated in this press release that Defendants would explore these options and seek HDE approval from the FDA for a subgroup of the angina patient population in the United States.

68. Defendants ultimately abandoned this approach later in the Class Period, but not before they misleadingly hyped this potential new designation as a victory and failed to disclose to investors that the FDA had suggested the HDE pathway principally because it repeatedly told Defendants that the current data for the Reducer was woefully inadequate to support efficacy.

Additionally, the FDA told Defendants that only an HDE pathway could be utilized because a HUD "is ***exempt*** from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under Section 514 and 515 of the" FDCA. *Id.* (emphasis added).

**A Crippling Judgment for Theft of Trade Secrets Destroys Neovasc's Ability to Raise Capital for the COSIRA II Trial for the Reducer**

69. On June 6, 2014, CardiAQ Valve Technologies Inc. (CardiAQ) filed a lawsuit against Neovasc for misappropriation of trade secrets, unfair and deceptive trade practices, breach of contract, and breach of an implied duty of good faith and fair dealing in the United States District Court for the District of Massachusetts. CardiAQ alleged that during the course of an ongoing business relationship, Neovasc misappropriated its trade secrets and breached a contract to develop Tiara, the transcatheter device in early clinical trials that seeks to treat mitral regurgitation. On May 19, 2016, a federal jury in Boston returned a verdict in favor of CardiAQ and found that Neovasc breached the non-disclosure agreement between the parties, misappropriated CardiAQ's trade secrets, and breached its duty of good faith and fair dealing. The jury awarded $70 million for the trade secret misappropriation claim.

70. After the verdict, the District Court enhanced the damages award and awarded pre- and post- judgment interest, bringing Neovasc's total liability to $112 million. Thereafter, the Company pursued an appeal of the crippling verdict. At the same time, the Company continued its discussions with the FDA on how to conduct a clinical trial in the United States. The Company succeeded in obtaining a stay of the judgment during the pendency of an appeal, but under the terms of a stay, Neovasc immediately deposited $70 million into an escrow account. Nevertheless, it still owed another $42 million to CardiAQ. On September 1, 2017, the Federal Circuit affirmed the verdict against Neovasc. On November 6, 2017, the FDA gave Neovasc the greenlight to conduct the COSIRA II study for the Reducer in the United States. However, seven days after

that, on November 13, 2017, the full judgment of $112 owed to CardiAQ became due, including $42 million that Neovasc had not yet paid.

71. Neovasc told investors in 2017 that it could not withstand the verdict and would declare bankruptcy unless it was able to raise funds from other sources to pay the remaining $42 million owed to CardiAQ. In an effort to pay the judgment, Neovasc completed two highly dilutive financing transactions with onerous terms (collectively, the "2017 Financing"), for aggregate gross proceeds of approximately $65 million. Most of this money was used to pay the $42 million balance of the damages and interest owed to CardiAQ. As part of the 2017 Financing, the Company was forced to issue warrants and notes with full-ratchet anti-dilution provisions, triggered with the issuance of any common stock by the Company at a price below their conversion price. The notes also contained reset provisions for conversion rates based on the future price of the Company's stock. The full effect of the 2017 Financing was the issuance of a large number of common shares as the Company's share price declined below the conversion price of the warrants and notes, and created massive dilution, hampering the Company's ability to raise capital or fund the COSIRA II study, which would cost tens of millions of dollars, throughout the Class Period—facts that the Company has admitted in its Annual Reports filed on Form 20-F for fiscal years 2018 and 2019.

72. For example, in the Company's Annual Report for 2018 filed on Form 20-F, Defendants stated that "[i]if we are unable to raise additional capital at an effective price per Common Share that is higher than the conversion price of the Notes, the anti-dilution provisions contained in the Notes may make it more difficult and more expensive to raise capital in the future." That Annual Report also stated that the Company was "still evaluating" the timing for

conducting the COSIRA II study, "funding being the largest impediment" given that it would cost tens of millions of dollars and take five years to complete.

73. Indeed, on July 24, 2020, Defendant Colen told *BioWorld*, a specialized industry magazine focused on news related to the biotechnology industry, that "I looked at it and said 'Wow, this [2017] financing is really, really bad,' and I didn't know if the company was going to make it."

74. That "really, really bad" 2017 Financing made it impossible to conduct any reliable or satisfactory clinical trial, including even the problematic COSIRA II study, given the staggering costs involved and the many years it would take to complete the study. For these reasons, Defendants chose to submit clinical data from the COSIRA trial and the REDUCER-I observational study even though they knew that the FDA already considered the results from both to be insufficient, and there was an extremely high-risk of non-approval as a result. Defendants did not disclose these facts to investors when they recklessly misled investors about the clinical data submitted to support the PMA for the Reducer.

**The FDA's Severe Criticisms of the Flawed Clinical Data Used to Support the PMA are Revealed at the Advisory Committee Meeting for the First Time**

75. On October 27, 2020, the Medical Devices Advisory Committee held a virtual meeting to discuss, make recommendations, and vote on the safety and efficacy of the Reducer in connection with the PMA. While most members of the panel found the Reducer could be safe for its intended use, the panel overwhelmingly voted 17 to one against on efficacy, and 13 to three against on whether the benefits of the device outweighed its relative risks. During the virtual advisory committee meeting, multiple members of the Coronary Interventional Devices Team in the Office of Cardiovascular Devices at the FDA shared their views on the clinical data provided by the Company to support the PMA for the Reducer. Their testimony severely criticized the

clinical data Defendants repeatedly touted throughout the Class Period, and the collective testimony was devastating. Dr. Raben, the FDA's team leader and lead presenter, observed that:

- the COSIRA trial presented great uncertainty concerning its benefit-risk profile because the preclinical animal studies did not meaningfully demonstrate the narrowing of the coronary sinus;
- there was significant uncertainty about the primary endpoint results due to issues with design, execution and analysis;
- interpretation of secondary endpoints presented challenges due to the limited sample size of the trial; and
- there were high levels of missing data and a lack of prespecified hypotheses.

76. Dr. Raben further confirmed that the IDE for the COSIRA trial was denied in 2010 because the FDA and Neovasc could not agree on the trial's design, so Neovasc chose to disregard the FDA's advice and conducted the trial outside the United States instead. He further noted that while the IDE for the COSIRA II trial was approved in 2017, the FDA had told Neovasc that it still had concerns and additional data beyond what was proposed to be gathered in COSIRA II would be required to support a PMA in the future. Additional members of the review team from the FDA provided the following criticisms on each specific deficiency of the clinical data used to support the Reducer's PMA that were equally severe:

Animal Studies

77. Dr. Ananbelle Crusan presented the FDA's views on the preclinical animal studies that Defendants touted to investors as demonstrating "excellent results." According to Dr. Crusan, the animal studies lacked even the bare minimum quality assurance to ensure validity and completeness of the data. Moreover, "there was no confirmation of sufficient device coverage by

neointima to restrict coronary sinus blood flow to the narrowed device central orifice, no confirmation of coronary sinus stenosis or elevated coronary sinus pressure, and limited evidence of improved myocardial contractility and blood flow." Tr. of the Advisory Committee Meeting held on October 27, 2020 at 82: 20-23.

Challenging Secondary Endpoints

78. Dr. Rona Tang, a statistician, noted that the COSIRA trial did not even have a primary safety endpoint. She also criticized the lack of statistical hypothesis for secondary endpoints and warned that with a large number of built-in secondary endpoints, the trial had a very serious potential for false positive findings. She further raised alarm about the high percentage of missing data for the secondary endpoints, which made interpretation challenging. Missing data was twice as common in the control group as compared to the Reducer group.

Design Defects

79. Dr. Tara Ryan from the FDA gave the lead presentation on the clinical data for the Reducer device. Dr. Ryan observed that 85% of the patients in the COSIRA study were male and 87% were white with an average age of 68. The study was thus not representative of the intended treatment population in the United States. Like other presenters, she also noted the importance of the missing data, particularly in the control group as opposed to the treatment group, which made it difficult to draw conclusions regarding the efficacy of the Reducer.

80. With respect to the REDUCER-I observational study, Dr. Ryan testified that it had no control group, which made it impossible for the FDA to interpret the data and draw any conclusions about efficacy. The data was also severely limited and hampered any ability to draw conclusions because there were only 20 patients in a single country who had follow-up data at the five year mark. In his closing remarks, Dr. Raben also identified very serious concerns about the

execution of the REDUCER-I study, concluding that it may be difficult to reach any conclusive result.

81. Dr. Ryan also observed that there was a substantial placebo effect, particularly for the relief of pain, and that while exercise tolerance testing has been used as an objective primary efficacy endpoint in clinical trials for similar devices, the COSIRA trial only used a subjective endpoint of angina. She further criticized the small size of the study as problematic, noting that the small sample limited the FDA's ability to draw conclusions about efficacy because a larger, adequately powered study could produce negative results.

82. She also noted that while an attempt was made to help ensure that the patient and family members of the patient remained blinded regarding what group the patient belonged to, there was no formal assessment or analysis regarding whether blinding was successful throughout the trial. In addition, "[b]ecause optimal medical therapy was not clearly defined [in the trial it was difficult] to know whether all patients were comparable with respect to being truly 'no option,' that is medication compliance, maximally tolerated doses of medications, and patient specific conditions precluding vascularization." Tr. of the Advisory Committee Meeting held on October 27, 2020 at 96: 17-20.

**Advisory Committee Concurs With the FDA's Severe Criticisms**

83. At the virtual meeting held on October 27, 2020, the advisory committee overwhelmingly agreed with the FDA's severe criticisms of the clinical data presented by the Company to support the PMA. Multiple members of the panel expressed concerns about the lack of a formal blinding questionnaire that would ask subjects to identify the study arm to which they believed they were assigned, and the lack of an objective primary endpoint as well as mounds of

missing data on secondary endpoints that made it impossible to determine whether there was evidence of efficacy.

84. Several members also criticized the basic contours of the COSIRA trial, including the gross imbalance in terms of ethnicity and gender and the failure to include a quantitative exercise stress test, which is routine in devices meant to alleviate angina symptoms. Indeed, in response to the criticisms from the panel about the failure to include a quantitative exercise test, Dr. Bram Zuckerman, the Director of the Office of Health Technology for Cardiovascular Devices, pointed out that the FDA had told the Company—way back in 2010—that a treadmill endpoint should be used as the standard in the COSIRA trial. Neovasc, however, disregarded the FDA's advice, and its refusal to include a treadmill endpoint was one of the primary reasons why the Company chose to conduct the trial abroad.

85. With respect to REDUCER-I, Dr. Keith Allen, a member of the panel, commented that Neovasc's request to consider data from an observational study was "very odd" and amounted to a request to first approve an unreliable device, and "then do the study that we would all like to see done, and so we absolutely need more and a better study." Tr. of the Advisory Committee Meeting held on October 27, 2020 at 216: 7-10. Dr. Zuckerman also told the panel that the FDA believed that the uncertainty of the risk-benefit profile for the Reducer could not be mitigated by an observational study, and that any uncertainty "would be better cleared up with a premarket randomized trial that has been referred to as COSIRA-II"—the trial Defendants refused to initiate due to the dire financial straits caused by their own theft of trade secrets. *Id*. at 217: 23-24. Dr. David Yu, another member of the advisory committee concurred, noting "that this is kind of a slippery slope where you can do a suboptimal study and then in a way work closely with the FDA

to try to smooth out the edges in an effort to get it approved. I just worry that we might be setting a precedent here that would get out of hand in terms of new devices." *Id.* at 218: 24-25-219: 1-2.

86. Shortly before the vote, multiple members of the advisory committee stated that things could have been different if the Company had not disregarded the FDA's severe criticisms of the COSIRA trial that was known years ago, listened to the agency's advice instead, and conducted a proper clinical study in accordance with the FDA's suggestions. For example, Doctor Jason Connor stated that "the [C]ompany got FDA feedback, chose not to accept it and ran the trial elsewhere, they have an open IDE with FDA feedback for a trial they chose not to initiate, and I think they had plenty of chances to run and obtain the efficacy that we all would like to have seen." *Id.* at 259: 5-8. Similarly, Dr. Ralph G. Brindis stated that "I'm really sorry that the [C]ompany opted not to take on this trial when the FDA offered it a couple of years ago, and we'd be further along in terms of potentially helping our patients with a device that potentially could be of value." *Id.* at 259: 15-20.

**Materially False and Misleading Statements Issued During the Class Period**

87. The Class Period begins on October 10, 2018, when Neovasc released a press release to announce that the FDA had designated the Reducer as a breakthrough device. In the press release, Defendant Colen made the following materially misleading statements:

> "We are pleased that the FDA has approved our request for Breakthrough Device designation for the Reducer. We will now start a process of further discussions and filings with the FDA, to obtain further guidance as to the regulatory pathway for entrance into the U.S. market. ***This designation supports our belief that this technology offers a significant benefit to patients suffering from refractory angina***," commented Fred Colen, Neovasc's President and Chief Executive Officer. "We look forward to working closely with FDA through this regulatory process."

88. The statements identified in Paragraph 87 were materially false or misleading when made because (a) the voluntary breakthrough device program does not alter the standard for safety

and efficacy under the FDCA and FDA regulations, (b) the designation, based on extremely limited data, merely meant that the device could potentially be effective if proper clinical studies were conducted, but did not mean that the Reducer offered a "significant benefit to patients," and (c) the statements omitted that the FDA had already determined and told Defendants that the COSIRA trial was not sufficient to demonstrate efficacy.

89. On February 20, 2019, during pre-market hours, Neovasc announced that the FDA had "recommended" that the Company collect additional pre-market blinded data before a PMA application could be submitted.

90. On this news, the price of Neovasc's common stock fell $0.10 per share, or 1.47%, to close at $6.70 per share on February 20, 2019.

91. However, despite this partial disclosure, the February 20, 2019 press release was materially misleading when made because the FDA had already told the Company that the COSIRA trial was deficient, and additional pre-market clinical data was not "recommended" but required.

92. On March 21, 2019, the Company held an earnings conference call to announce financial results for the fourth quarter of 2018. During this conference call, Defendant Colen made the following materially misleading statements:

> ***Our REDUCER-I post-market observational study continues to enroll patients across Europe at 20 active centers. Enrollment has now reached 195 of 400. Data from the study, COSIIRA*** **[sic]** ***study, as well as published data from several physician initiated studies continues to reflect the very positive safety profile and improvement in patient's angina therefore improving patient's quality of life following Reducer implantation.***
>
> *****
>
> The FDA review team has since followed up from this meeting and recommended that despite Breakthrough Device Designation, we collect additional pre-market blinded data prior to PMA submission. ***While we respect their current***

> ***recommendation, we will continue to have discussions with the FDA and their senior management in attempts to bring this promising refractory angina device therapy which has been available to patients in Europe since 2015 with demonstrated quality of life improvement and great safety profile to U.S. patients as soon as possible.*** In that same vein, we recently announced the second successful implantation of the Reducer in the United States under Compassionate Use.

93. The statements identified in Paragraph 92 were materially misleading when made because Colen omitted to disclose that (a) the FDA had already determined and told Defendants that the COSIRA trial was not sufficient to demonstrate efficacy, (b) the FDA consistently maintained in non-public regulatory conversations with the Company that it needed to collect additional premarket clinical data, (c) the FDA at no time told the Company that REDUCER-I would excuse the identified design and conduct defects of COSIRA I, or the COSIRA II trial that the Company had told the FDA it would conduct but did not conduct, and (d) the omission of all these facts rendered Colen's attempt to paint the disagreement with the FDA as one that could be easily resolved as extremely misleading.

94. During the March 21, 2019 earnings conference call, an analyst specifically inquired about why the FDA had requested additional premarket clinical data for the Reducer, and Colen made the following materially misleading statements in response:

> **Q: Destiny Buch**
>
> Okay, great. That's incredibly helpful. And then within the U.S., I know you mentioned that the FDA had asked you to gather a bit more data prior to another PMA submission. Can you tell us where you stand on that now and are you able to give us a bit more color on when you expect to submit?
>
> **A: Fredericus Colon:**
>
> Yeah. ***So, you said this correctly and basically what we are now in the process of doing is organizing a next meeting with the FDA to talk again about all the clinical data that we have and understand better why they want the additional data because we believe we have essentially a lot of the data that they would like to see for an approval.***

> ***But then, if they clarified to us why they want to see additional data, we would also like to understand what kind of a size of a clinical study they are thinking about. So, there's more clarification required as to why they're asking for this. And then once we understand that, what kind of size for clinical study they are thinking about.*** And I think that that we'll understand all that a lot better in the next month or two, through the Breakthrough Designation we do have relatively quick access to FDA officials, but it still takes time to get it all scheduled, et cetera.

95. The statements identified in Paragraph 94 were materially misleading when made because Colen omitted to disclose that (a) Defendants already understood why the FDA wanted additional data given the FDA's warning about trial defects in COSIRA and further discussions regarding the planned (but never conducted) COSIRA II trial, which the FDA also told Defendants was insufficient to demonstrate efficacy on its own and (b) the trial defects that the FDA had warned Defendants about for almost a decade went well beyond the size of the patient population in the trial, and included, among other things, the demographic makeup of the trial, the placebo effect, the lack of blinding confirmation, the inconclusive results from animal studies, the significant missing data, and the lack of a proper exercise stress test.

96. On March 21, 2019, the Company also filed with the SEC an Annual Report for the fiscal year 2018 on Form 20-F ("the 2018 Annual Report"). This Annual Report was signed by Defendants Colen and Clark and contained their certifications pursuant to the Sarbanes Oxley Act of 2002 ("SOX"). The Annual Report falsely asserted that "Reducer has demonstrated excellent results in multiple animal studies."

97. This statement identified in Paragraph 96 was demonstrably false because, as confirmed by Dr. Raben, the lead presenter for the FDA, (a) the animal studies did not "confirm tissue coverage to restrict coronary sinus bloodflow to the Reducer's central orifice," and (b) the animal studies could not provide a basis to show that the Reducer performed as intended because the studies did not measure "the presence of severity of [the] coronary sinus," "a coronary sinus

pressure gradient across the device," or "the association of a coronary sinus stenosis or a coronary pressure gradient with reduced angina or ischemia." Tr. of Advisory Committee Meeting at 215: 9-16.

98. The 2018 Annual Report further contained the following materially misleading statements regarding potential risks that third parties would perceive the Company's clinical trials unfavorably or that the clinical trials themselves may have unfavorable results:

> ***Our products are continually the subject of clinical trials conducted by us, our competitors, or other third parties, the results of which may be unfavorable, or perceived as unfavorable, and could have a material adverse effect on our business, financial condition, and results of operations.***
>
> The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical experiences and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product. Failure to successfully complete these trials or procedures in a timely and cost-effective manner ***could*** have a material adverse effect on our prospects. Clinical trials or procedures ***may*** experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures ***may*** be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures ***may*** not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be suspended or terminated by us or regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks.

99. The statements identified in Paragraph 98 were materially misleading when made because they omitted to disclose that (a) the failure to conduct a proper clinical trial had already had a material adverse impact on the Company's prospects, (b) the COSIRA trial suffered a setback nearly a decade ago when the FDA told the Company that its design and parameters were

insufficient to support efficacy and again raised concerns about the lack of a formal blinding assessment, the lack of a treadmill exercise endpoint, and missing data from animal studies and secondary endpoints that made interpretation of its results impossible, (c) the REDUCER-I, the "long-term" post-market surveillance study, did not support long-term results because it only had five-year data from 20 patients in a single country and was not a substitute for a preapproval study in the first place.

100. On May 9, 2019, the Company issued a press release and then a corrected press release revising language not relevant to this litigation to announce the financial results for the first quarter of 2019. Both press releases contained the following materially false and misleading statements:

> The REDUCER-I post-market observational study has enrolled 199 of 400 patients across Europe at 21 active centers. ***Data from this study, the COSIRA study, as well as published data from several physician-initiated studies continues to reflect the very positive safety profile and improvements in a patient's refractory angina, therefore improving the patient's quality of life following Reducer implantation.***

101. The statements identified in Paragraph 100 were materially false and misleading when made because (a) the FDA had already told the Company that the COSIRA trial could not establish the efficacy of the Reducer or establish "improvements in a patient's refractory angina," and (b) Defendants omitted to disclose that the REDUCER-I study was not a sufficient substitute for a robust preapproval clinical trial that the FDA told them was required.

102. On May 22, 2019, the Company announced that the International Journal of Cardiology had published a positive article discussing the results of an extremely small study of 50 patients who used the Reducer. In this press release, Defendant Banai made the following misleading statements:

> This study shows us that the Reducer has a sustained therapeutic effect at two years across a large patient population. In addition, we believe this study provides

> valuable long-term safety data that further supports cardiologists use of the Reducer as a therapeutic option for patients suffering from refractory angina. ***This data supports our belief that the Reducer offers refractory angina patients a safe and effective treatment option, filling a void in a market where there are currently limited therapeutic options.***

103. The statements identified in Paragraph 102 were materially misleading when made because they omitted to disclose that Banai knew that (a) the FDA told Neovasc that the COSIRA study was grossly insufficient to demonstrate efficacy many years before these misleading statements were made, and (b) the known, inherent flaws of the COSIRA trial and the REDUCER-I observational study undermined any alleged beliefs about the Reducer's effectiveness.

104. On July 12, 2019, the Company announced that, based on feedback from the FDA, Neovasc would explore an HDE approval pathway to determine whether the Reducer could receive a HUD designation. In this press release, Defendant Colen made the following materially misleading statements:

> ***We are encouraged by the outcome of our discussions with the FDA on the clinical evidence and the potential pathway to the U.S. market for the Reducer.*** The FDA's proposed alternative approaches, including a potential HDE pathway, would provide a meaningful treatment option for those patients suffering from the worst angina symptoms and who are desperate for a novel treatment in the fastest possible manner. ***This guidance from the FDA represents a potential substantial improvement over the original timeline we expected to bring this novel breakthrough medical device therapy for the treatment of refractory angina to the U.S. market.***

105. The statements identified in Paragraph 104 were materially misleading when made because Colen omitted to disclose that the FDA suggested the HDE pathway for the Reducer because the Company lacked sufficient evidence of efficacy and HUDs do not require the sponsor to demonstrate efficacy.

106. On August 7, 2019, the Company held an earnings conference call to announce the financial results for the second quarter of 2019. In response to analyst questions about the HDE

pathway, Defendant Colen claimed that the Company was "quite encouraged with the discussions we've had with the FDA," and that the FDA's suggestions regarding the HDE pathway constituted "positive momentum that we have developed in the discussions with the FDA."

107. The statements identified in Paragraph 106 were materially misleading when made because (a) the feedback from the FDA was neither "encouraging" nor constituted "positive momentum," and (b) Colen omitted to disclose that the FDA suggested the HDE pathway for the Reducer because the Company lacked sufficient evidence of efficacy and HUDs do not require the sponsor to demonstrate efficacy.

108. Ultimately, Defendants quickly abandoned exploring an HDE pathway given the serious limitations on profit based on the 8,000 patient cap for a HUD in the United States.

109. On November 1, 2019, Neovasc announced that it would submit a full PMA application to the FDA for the Reducer. In a press release, the Company made the following materially misleading statements:

> "We believe that ***the totality of clinical evidence from the COSIRA study, REDUCER-I European Post-Market study (with over 200 of 400 patients enrolled), and multiple independent studies published in peer-reviewed journals, will provide reasonable assurance of safety and effectiveness to support a PMA***. Neovasc plans to submit the PMA application prior to the end of 2019 with a request for an Advisory Panel meeting", said Fred Colen, President and CEO of Neovasc. "While any pathway to U.S. market approval by the FDA carries considerable risk, we believe the full PMA application pathway brings the best chance of success within reasonable cost and time constraints. After evaluating the different options, we concluded that the Humanitarian Use Device ("HUD") pathway would likely not be a viable option based on the definition of an HUD device within the FDA Guidance and that the PMA pathway would be our best option to bring Reducer to the U.S. market to treat refractory angina patients. While an additional post-market study will most likely be needed and the body of real-world evidence continues to grow, ***the Company believes that the clinical evidence already available will be sufficient to not further delay the availability of this Breakthrough medical device for the treatment of U.S. patients***."

110. The statements identified in Paragraph 109 were materially misleading when made because they omitted to disclose that (a) the FDA had repeatedly told Defendants before the PMA was submitted that the COSIRA trial was grossly insufficient to demonstrate the efficacy of the Reducer, (b) the FDA had told Defendants that the REDUCER-I observational study was not a meaningful substitute for a robust, well-controlled clinical trial conducted before approval, and hence (c) the totality of the clinical evidence did not support the Reducer's efficacy or ensure that there would be no further delay of the Reducer's approval.

111. On November 7, 2019, the Company released a press release to announce the financial results for the third quarter of 2019. This press release contained the same materially false and misleading statements identified in Paragraph 102, which were false and misleading for the same reasons described in Paragraph 103.

112. On November 7, 2019, the Company also held an earnings conference call to discuss the financial results for the third quarter of 2019. During this conference call, Defendant Colen made the following materially misleading statements:

> Additionally, we have taken concrete steps on the path to approval in the U.S. market. To that end, we decided to submit a full PMA application to the FDA before the year is out. ***We believe that the totality of clinical data available now from the COSIRA study, new and additional data from the REDUCER-I European post-market study, with interim analysis of over 200 from 400 patients enrolled, with up to 2-year follow-up as well as multiple independent published studies should provide reasonable assurance of safety and effectiveness to support a PMA.*** We believe that taking this more rigorous path demonstrate the confidence we have in the size of the market opportunity and in the safety and efficacy of Reducer.
>
> However, any pathway to U.S. market approval by the FDA carries considerable risk. And there can be no assurance that the PMA will be approved by the FDA in a timely manner or at all. We continue to focus on the commercialization of this product in the European market and to obtain approval in the U.S. market. ***As of November 5, 2019, the REDUCER-I post-market observational study has enrolled 224 of 400 patients across Europe at 23 active centers. Additional new clinical data from this study, the original randomized sham controlled COSIRA study as well as published data from several physician initiated studies continues***

> ***to demonstrate the very positive safety profile as well as the effectiveness for the treatment of a patient's refractory angina; therefore, improving the patient's quality of life following Reducer implantation.*** We believe that these clinical trial results, along with an expanded sales force in Europe, will continue to raise awareness of Reducer with health care providers. It is important to note here that there are currently no devices on the market that compete with Reducer, a key advantage in our commercialization efforts.

113. The statements identified in Paragraph 112 were materially misleading when made because they omitted to disclose that (a) the FDA had already told Defendants that the COSIRA trial was grossly insufficient to demonstrate the efficacy of the Reducer, (b) the FDA had told the Defendants that the REDUCER-I observational study was not a meaningful substitute for a robust, well-controlled clinical trial conducted before approval, and hence (c) the totality of the clinical evidence did not support the Reducer's efficacy or its effectiveness for the treatment of refractory angina.

114. At the same conference call, in response to a specific analyst inquiry about why discussions with the FDA had led the Company to conclude that a PMA should be submitted, Defendant Colen made the following materially misleading statements:

> **Q - Danielle Joy Antalffy**
>
> Got it. Congrats on that hire. My next question for you is on the PMA filing for Reducer. I'm just curious if you can provide any color behind your -- I know you guys have been in conversation with the FDA. Any color you can give that gave you at least enough comfort to take this path as to sort of what -- how your conversations went with FDA there?
>
> **A - Fredericus A. Colen**
>
> Yes. So as you know, we have been working very closely with the FDA to explore the best path to market for the Reducer in the U.S. And I think we have explained already publicly some of the issues we're running into going down the path of an HUD. The 8,000 patient restriction is somewhat problematic because there's a large patient population that can benefit from this device. And the device is not just built for a Class 4 patient population. But for a much broader patient population. So we were running with best efforts on all sides, including us as well as the FDA, into some snags there.

> ***The other point is that we have been very fortunate to have now enrolled over 200 patients of the 400 in our REDUCER-I European post-market study. And we have started to analyze the data for interim analysis of 200 patients, which will also be published sometime around the middle of next year. But that data is also very important real-world data that we want to add to the strong COSIRA data that we have, the sham-controlled clinical data. And put together a comprehensive clinical package for the FDA as part of this PMA submission. So I think that was the other part of this, Danielle, that we felt we have not only a very good sham-controlled randomized clinical study in the terms of COSIRA but that we now also have real strong additional post-market data that we believe might support the safety and efficacy of a full PMA submission. So that's basically the background that you were looking for.***

115. The statements identified in Paragraph 114 were materially misleading when made because they omitted to disclose that (a) the FDA had already told Defendants that the COSIRA trial was grossly insufficient to demonstrate the efficacy of the Reducer, (b) the FDA had told Defendants that the REDUCER-I observational study was not a meaningful substitute for a robust, well-controlled clinical trial conducted before approval, and hence (c) Colen's references to "the strong COSIRA data," "a very good sham-controlled randomized clinical study" and "real strong additional post-market data" were false or misleading when made.

116. On November 13, 2019, Defendant Colen attended the Credit Suisse Healthcare Conference in Scottsdale, Arizona and made the following false statement about the COSIRA trial:

> Yes. ***We have -- our study from Europe, we have clinical data to demonstrate the effectiveness of the device, the real effect of a significant reduction in emergency department visits.*** So we believe, in subsequent discussions with CMS, that CMS is going to be interested to see that. And being able to bring a therapy to the market that benefits patients. But also benefits the health care system in terms of cost is always a very positive thing. So we're very excited about that.

117. The statements identified in Paragraph 116 were materially false when made because (a) the COSIRA study was inherently flawed from the start and did not "demonstrate the effectiveness of the device," and (b) the FDA had already warned Defendants that the COSIRA trial was insufficient to demonstrate efficacy.

118. On December 31, 2019, the Company announced that it had submitted a PMA for the Reducer to the FDA.

119. On January 15, 2020, the Company announced that the PMA for the Reducer had been accepted by the FDA for further review.

120. On March 3, 2020, the Company released a press release touting a study in a European publication that lauded the Reducer for demonstrating "objective improvement in exercise capacity and oxygen kinetics." In this press release, Defendant Banai made the following materially misleading statements:

> Both of these studies demonstrate that the Coronary Sinus Reducer can not only improve symptoms and quality of life, but also provide objective improvement of ischemia, myocardial performance and coronary microvascular blood flow. ***We believe the Reducer has truly become an effective trusted cardiac treatment option in many countries.***

121. The statements identified in Paragraph 120 were materially misleading when made because Banai omitted to disclose that (a) the FDA had already told the Defendants that the COSIRA trial was grossly insufficient to demonstrate efficacy under United States standards because Defendants refused to include an objective treadmill endpoint, (b) the structural defects of the COSIRA trial did not support improvements in "exercise capacity or oxygen kinetics," and hence (c) it was misleading to tout foreign publications to claim that the Reducer "has truly become an effective trusted cardiac treatment option."

122. On March 30, 2020, the Company held a conference call to announce financial results for the fourth quarter of 2019. During this conference call, Defendant Colen made the following materially misleading statements:

> ***We believe that the totality of data from the COSIRA study [with REDUCER-I] European post-market study with over 400 or 400 -- I'm sorry, with over 200 of 400 patients enrolled, and multiple independent published studies will provide reasonable assurance of safety and efficacy to support the PMA.*** We hope that

> taking this more vigorous path demonstrates our confidence that we have in the safety and efficacy of the Reducer.

123. The statements identified in Paragraph 122 were materially misleading when made because Colen omitted to disclose that (a) the FDA had already told the Company that the COSIRA trial was grossly insufficient to demonstrate the efficacy of the Reducer, (b) the FDA had told Defendants that the REDUCER-I observational study was not a meaningful substitute for a robust, well-controlled clinical trial conducted before approval, and hence (c) reliance on both the COSIRA trial and the REDUCER-I study could not support any confidence in the efficacy of the Reducer.

124. On March 30, 2020, the Company also filed its annual report on Form 20-F with the SEC for the fiscal year that ended on December 31, 2019 ("the 2019 Annual Report"). The 2019 Annual Report contained the same false and misleading statements that were contained in the 2018 Annual Report, identified in Paragraphs 96 and 98 above, and these statements were false and misleading for the same reasons explained in Paragraphs 97 and 99.

125. On July 24, 2020, *BioWorld* published an article entitled "A bleak financial history behind it, Neovasc boosted by study of its refractory angina device." This article quoted the following materially misleading statement made by Defendant Little:

> ***The results of the Reducer I, an international, three-arm observational study of an initial 241 patients with refractory angina were remarkable.*** At six months follow up to all the way out to two years follow up, 70% of patients suffering from the most debilitating angina classes 3 and 4 fell to 15.9***%. That was a dramatic impact on really desperate patients who had tried everything else.***

126. The statements identified in Paragraph 125 were materially misleading when made because Little omitted to disclose that the REDUCER-I study (a) had no control group, which made it difficult to interpret the results, (b) of the 241 patients referenced, Defendants in fact had only obtained from 20 patients in a single country follow-up data at the five-year mark, (c) the

FDA had expressed serious concerns about the execution of the REDUCER-I study and doubted whether the observational study could be completed successfully, and (d) the FDA had told Defendants that the REDUCER-I study was not an adequate substitute for a robust, premarket, well-controlled randomized clinical trial.

127. On August 6, 2020, the Company held a conference call to announce the financial results for the second quarter of 2020. During this conference call, Defendant Colen made the following materially misleading statements:

> Also during the quarter, we announced positive interim results from the REDUCER-1 study of refractory angina patients. The primary efficacy endpoint of the study is improvement in chest pain or angina, as measured by the Canadian Cardiovascular Society grading system. 70% of patients saw improvement in their symptoms by at least 1 CCS class that was maintained through 3 years. All but about this, 34% of patients saw an improvement in their symptoms by at least 2 CCs classes that was also maintained through 3 years. ***We believe data like this support Reducer as the only available device to effectively treat refractory angina.***

128. The statements identified in Paragraph 127 were materially misleading when made because Little omitted to disclose that the REDUCER-I study (a) had no control group, which made it difficult to interpret the results, (b) of the 241 patients referenced, Defendants in fact had only obtained from 20 patients in a single country follow-up data at the five-year mark, (c) the FDA had expressed serious concerns about the execution of the REDUCER-I study and doubted whether the observational study could be completed successfully, and (d) the FDA had told Defendants that the REDUCER-I study was not an adequate substitute for a robust, premarket, well-controlled randomized clinical trial.

**The Truth Gradually Emerges**

129. On October 27, 2020, the advisory committee met to discuss, make recommendations, and vote on the safety and efficacy of the Reducer. At this meeting, the FDA gave a full accounting of the extremely serious problems identified in the clinical data used to

support the PMA for the first time and that are fully described in detail in Paragraphs 75 through 82. The advisory committee concurred with many of the FDA's serious criticisms that are fully described in Paragraphs 83 through 86.

130. As a result of the FDA criticisms discussed at the advisory panel, which the FDA had communicated to the Company for many years prior to the Class Period, the advisory committee voted 17 to one that the Company failed to establish efficacy of the Reducer and 13 to three that the Company failed to establish that the benefits of the Reducer outweighed its risks.

131. On this news, the price of the Company's common stock fell $0.77 per share, or 42%, to close at $1.06 per share on October 28, 2020, on unusually heavy trading volume.

132. On November 6, 2020, the Company held a conference call to announce the financial results for the third quarter of 2020. At this conference call, instead of coming clean, Defendant Colen further dissembled to investors. In response to an analyst question about the advisory committee's final recommendation, Colen falsely claimed that the advisory committee gave the Reducer "a positive mark as related to benefit over risk," a categorically false statement that was inconsistent with the actual committee vote of 13 to three against on the Reducer's benefit-risk profile. In addition, to cover up for his repeated failure to fully disclose the truth to investors, Colen falsely claimed that general written FDA guidance favored an approach that the FDA had expressly told him was not justified by the specific clinical data the Company possessed:

> ***There also were specific details of relevant FDA guidance documents that we believe supported the path we took to submitting the PMA. A, from December 2018, breakthrough devices program, I quote, "As with all devices subject with PMA, breakthrough devices subject to a PMA must still need the statutory standard of reasonable assurance of safety and effectiveness at the time of approval."***
>
> ***For PMA, the designated as breakthrough devices, FDA intends to use timely post-market data collection when scientifically appropriate to facilitate expedited and efficient development and review of a device.***

B, from August 2019, consideration of uncertainty and major benefit risk determinations in medical device premarket approvals, de novo classification and humanitarian device exemption. ***Example 1a from this guidance discusses a breakthrough device intended to treat a treatment-resistant condition. In that example, they discuss 3 scenarios of uncertainty. The greater the level of uncertainty, the greater the reliance on post-market data collection. As I stated earlier, we did submit a robust post-market study for consideration.***

***C, from August 2019. Factors to consider when making benefit risk determinations in medical devices, premarket approval and de novo classification. Uncertainty, patient perspective, availability of alternative, risk mitigation, novel technology addressing unmet medical needs.***

***And finally, D, from April 2015, balancing premarket and postmarket data collection for devices subject to premarket approval, I quote, "Getting the right balance between premarket and postmarket data collection, specifically, where appropriate, a greater reliance on postmarket collection, including real-world data collection, can reduce the extent of premarket data collection and directly impact when patients will have access to this high quality, safe and effective medical devices."***

Taking into consideration all guidance documents, and the volume of data we had, especially given the focus of the program to provide more timely access of innovative medical devices for patients with unmet need, we choose to submit a PMA in December of 2019 with a request for an advisory panel meeting.

133. The statements identified in Paragraph 132 were materially misleading when made because:

(a) the FDA repeatedly told the Company that the COSIRA trial was inherently flawed and again told Neovasc to collect additional clinical data in early 2019 despite being aware of the REDUCER-I observational study, which was started on March 2016 and was not complete at the time the PMA was submitted;

(b) the examples contained in the FDA's Guidance, published on August 30, 2019, on the considerations of uncertainty assume that premarket evidence meets the performance goal ***before*** the FDA considers observational data, not the other way around;

(c) the FDA's August 30, 2019 Guidance on the factors to consider when making benefit-risk determinations in no way supported approval because, according to that Guidance, (i) uncertainty dramatically increases because of "poor design or poor conduct of clinical trials," problems that the FDA had privately warned Defendants about for years with respect to COSIRA, (ii) patient perspectives are irrelevant if "the probable risks outweigh the probable benefits for all reasonable patients," (iii) the probable benefits ***must*** still outweigh the probable risks even if no other alternative treatment is available, and (iv) the FDA had already told Defendants numerous times for over a decade that Neovasc needed additional clinical data to assess the Reducer's benefit-risk profile, including in February 2019 after the REDUCER-I observational study was commenced, confirming that the FDA did not consider the REDUCER-I study to be an adequate substitute;

and (d) the FDA's Guidance from April 2015 expressly states that the FDA may only consider greater preapproval uncertainty, "***as long as the premarket data still support a reasonable assurance of safety and efficacy***," which the COSIRA trial did not, and notes that observational surveillance data is most helpful when minor risks are raised in the approval stage or to assess long-term benefit-risk when short-term benefit-risk is established or when the FDA already has experience with the device type or to assess rare adverse events—***none*** of which applied at all to the Reducer.

134. On January 15, 2021, the Company announced in a press release that the FDA had rejected the PMA for the Reducer.

135. On this news, the Company's stock price fell by 8%, to close at $1.10 per share on the next trading day, which was January 19, 2021.

136. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages. These drops eliminated over 40% of the Company's stock price, collectively constituted a massive volume of shares, and the Company's stock price has plummeted from $6.50 in the beginning of the 2019 to barely over $1 today.

**Additional Allegations of Scienter**

137. Defendants were aware of the FDA's serious criticisms and concerns regarding the COSIRA trial many years before the beginning of the Class Period. This is clear from the FDA's presentation at the virtual meeting of the advisory committee held on October 27, 2020, and the specific testimony of Dr. Raben, Dr. Ryan and Dr. Zuckerman. As Dr. Raben testified, the same concerns raised by the FDA at the advisory committee meeting were first discussed with the Company in 2010, but Neovasc chose to disregard the FDA's advice and conducted the COSIRA trial abroad. Dr. Raben further testified that while the IDE for the COSIRA II trial was approved in 2017, the FDA had told Neovasc that even this trial would not be sufficient because additional data beyond what was proposed in that study was required to support any PMA in the future.

138. Dr. Zuckerman similarly confirmed that one of the major design defects of the COSIRA trial was the failure to include a treadmill endpoint, and this failure was a major sticking point discussed with the Company in 2010, but Neovasc chose to utilize a subjective endpoint instead and conducted the COSIRA trial abroad.

139. Furthermore, Defendants had constant communication with the FDA at an intense level due to the greater communication with the FDA afforded by the Breakthrough Device

Program, including a specialized review team, higher level management oversight at the FDA, and regular Sprint discussions. This fact cannot be disputed given Colen's repeated references to Sprint discussions concerning the Reducer throughout the Class Period, and the fact that the FDA again told the Company to collect additional premarket blinded data in early 2019 and then suggested an HDE pathway in the summer of 2019 because the Reducer could not meet the FDCA's statutory requirements for efficacy. Indeed, at the advisory committee meeting held on October 27, 2020, Dr. Ryan explicitly noted that "***[f]irst, we would like to relate to Panel members that study limitations have been discussed with the Sponsor, both in writing and during multiple in-person and teleconference interactions.*** FDA worked with the Sponsor to develop a protocol called COSIRA-II, a study protocol that was approved under an IDE application in November 2017." Tr. of the Advisory Committee Meeting held on October 27, 2020 at 95: 6-10 (emphasis added). There is thus no question that the Defendants here were aware of the FDA's serious criticisms and concerns of both the COSIRA trials and the REDUCER-I post-market surveillance study long before they chose to submit the PMA.

140. In addition, it is virtually inconceivable that the Defendants were unaware of the high risk of non-approval given the FDA's communications with them, and the fact that Banai claims to be "one of Israel's leading Cardiologists," and Colen, Clark and Little have the requisite background and experience to be in a position to know both about the data needed to prove efficacy as well as the FDA's regulatory framework for the approval of medical devices. Despite this knowledge and these experiences, all four Defendants knowingly or recklessly misled investors about the strength of the clinical data utilized to support the PMA for the Reducer, but failed to disclose the devastating facts that seriously cut against their positive spin.

**Defendants Profited From Touting the Clinical Data Used to Support the PMA**

141. Defendants Colen, Clark and Little profited from illusory "objectives pertaining to the development of the Reducer" throughout the Class Period. For fiscal year 2018, Colen was paid a salary of $390,000, but his bonus was almost equal to his salary in the amount of $349,500 based on illusory objectives related to the "development" of the Reducer. Similarly, for fiscal year 2018, Clark was paid a salary of $257,256, and $153,067 as a bonus tied to the illusory objectives.

142. For fiscal year 2019, Colen was paid a salary $401,700, and a bonus tied to illusory objectives for the Reducer in the amount of $369,461. For the same fiscal year, Clark was paid a salary of $270,797 in US dollars, and a bonus of $221,130 in Canadian dollars. Little, who joined the Company in November 2019 and was meant to be paid an annual salary of $300,000 immediately profited from the illusory objectives too, earning a cash award of $23,746 in 2019.

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

143. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf all persons and entities that purchased or otherwise acquired Neovasc common stock between October 10, 2018 and January 15, 2021, both dates inclusive, and were damaged thereby (the "Class"). Excluded from the Class are Defendants herein, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

144. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Neovasc common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Neovasc or its transfer agent and may be notified of the

pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

145. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

146. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

147. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Neovasc;
- whether the Individual Defendants caused Neovasc to issue false and misleading statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of Neovasc common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

148. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

149. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Neovasc's common stock is traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Neovasc common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts materialized or were disclosed, without knowledge of the omitted or misrepresented facts.

150. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

151. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Plaintiff's claims are based primarily on Defendants' omission of material information in violation of a duty to disclose such information, as detailed above.

## COUNT I

**(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)**

152. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

153. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5 promulgated thereunder.

154. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of common stock. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Neovasc common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Neovasc common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

155. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the materially misleading statements described above that were designed to influence the market for Neovasc securities. The statements described above were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Neovasc's products and business prospects.

156. Defendants either had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

157. Information showing that Defendants acted either knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the most senior executives of Neovasc, the Individual Defendants had knowledge of the details of Neovasc's internal affairs.

158. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of Neovasc's public statements. As senior executives of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Neovasc's business, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading statements, the market price of Neovasc's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Neovasc's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Neovasc common stock at artificially

inflated prices and relied upon the price of the common stock, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

159. During the Class Period, Neovasc common stock traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Neovasc common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Neovasc common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Neovasc common stock declined upon public disclosure or materialization of the facts alleged herein to the injury of Plaintiff and Class members.

160. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

161. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure or materialization of the risk that the Company had been disseminating misleading statements to the investing public regarding its ability to develop and commercialize the Reducer.

## COUNT II

**(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)**

162. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

163. During the Class Period, the Individual Defendants participated in the operation and management of Neovasc, and conducted and participated, directly and indirectly, in the conduct of Neovasc's business affairs. Because of their senior positions, they knew the adverse non-public information that rendered Neovasc's public statements false and misleading.

164. As senior executives of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Neovasc's products and results of operations, and to correct promptly any public statements issued by Neovasc which had become materially false or misleading.

165. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the Company's statements, which Neovasc disseminated in the marketplace during the Class Period concerning Neovasc's products and business. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Neovasc to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Neovasc within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Neovasc common stock.

166. Each of the Individual Defendants, therefore, acted as a controlling person of Neovasc. By reason of their senior positions at Neovasc, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Neovasc to engage in the

unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Neovasc and possessed the power to control the specific activities, which comprise the primary violations about which Plaintiff, and the other members of the Class complain.

167. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Neovasc.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class Representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: March 19, 2021

Respectfully submitted,

**POMERANTZ LLP**

*/s/ Omar Jafri*

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